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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,246

Applicant(s)

GALA ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Applicant's response to the previously set forth restriction requirement is acknowledged. Upon further consideration, a new restriction requirement is set forth. This restriction differs from the previously set forth restriction primarily in that this restriction uses LINKING CLAIM practice instead of the previously set forth election of species.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, 10, 11, 13, 22-23, and 24-25, drawn to methods for detection of mycobacterium, classified in class 435, subclass 6.
 - II. Claim 12, drawn to methods for identification of new mycobacterium sequences, classified in class 435, subclass 6.
 - III. Claims 14-21, drawn to mycobacterium probes, primers and kits containing the same, classified in class 536, subclass 24.32.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions insofar as they are drawn to distinct methods that have separate effects and modes of operation. The methods of group I are drawn to the detection of specific mycobacterium within a sample, while the methods of group II are drawn to the discovery of new mycobacterium sequences within a sample.

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3. Inventions I and III and inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention III can be used in a variety of mycobacteria detection assays but also in nucleic acid purification assays and assays for the discovery of new sequences.
4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-III require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

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examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further Restriction Requirement Applicable to each Group

5. Within the three general groupings of inventions listed as groups I, II, and III above, there are a multiplicity of distinct inventions which are identifiable by recitation of specific SEQ ID NO.

6. Each SEQ ID NO: represents a nucleic acid sequence with separate and distinct structural properties, and the search and examination of each individual sequence requires a separate search of the patent and non-patent literature. Instant SEQ ID NO: 1-74 contain fragments of nucleic

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acids that were isolated from and represent at least eighteen different species of mycobacteria. A search of all of the recited sequences with a method claim or within a product claim would pose a serious burden to the examiner and to PTO search resources.

7. In response to this restriction requirement, for the elected group from groups I-III as recited above, a further restriction requirement is set forth.

For group I:

(a) If group I is elected, applicant should further elect a single nucleic acid sequence from SEQ ID NO: 1-74. For the elected sequence, applicant should further identify any additional sequences disclosed within the specification that are FRAGMENTS of the elected sequence, all appropriate fragments will be examined in claim 3.

(b) Further, for group I, if the first sequence is one of SEQ ID NO: 8-54 or 57-75, applicant should further elect a second sequence for examination in claim 5.

(c) Further, for group I, if the first sequence is one of SEQ ID NO: 1-54, applicant should further elect a second sequence to be used in a primer pair with the first elected sequence from those listed in claim 9.

(d) Further, for group I, applicant should elect a primer pair and/or probe as appropriate for examination with claim 13. For example, if the first elected sequence is SEQ ID NO: 66, applicant should also elect a primer pair from SEQ ID NO: 1-7 for examination.

(e) If the elected sequence is SEQ ID NO: 68, applicant should further elect an additional sequence from SEQ ID NO: 8, 27-29, and 50-58 for examination with claims 24 and 25.

For group II:

Applicant should select a single primer pair from SEQ ID NO: 1-7.

For group III:

(a) If group II is elected, applicant should further elect a single nucleic acid sequence from SEQ ID NO: 1-54 and 57-74. For the elected sequence, applicant should further identify any additional sequences disclosed within the specification that are FRAGMENTS of the elected sequence.

(b) Further, for group II, if the first elected sequence is one of SEQ ID NO: 57-74, applicant should identify the sequences recited in claim 15 that are fragments of the elected sequence.

Within an elected group, only claims will be examined that specifically recite the elected sequence.

8. Within group I, claims 1, 4, 6, and 8 link(s) each of the separate and distinct inventions represented by individual SEQ ID NO. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1, 4, 6, and 8. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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9. There are no linking claims in groups II or III.

10. Upon further consideration of the subject matter in the instant claims, it was determined that each individual recited sequence is not properly classified as a "species" of invention because the recited sequences within the methods and product claims do not share a common utility and they do not have a substantial structural similarity. They do not share a common utility because the sequences are from separate species of mycobacteria and are useful for detecting and differentiating the same. Further, each sequence has a unique ordering of nucleotides and a unique structure that is not shared with the other, this structure results in unique binding properties and therefore the sequences do not share a common structure.

11. The previous response to the restriction requirement elected group I and SEQ ID NO: 66. If a similar response is filed after this restriction requirement, claims 1-6, 8, 13, 22, and 23 will be examined. If applicant wishes to maintain that election, applicant is requested to affirm that election in response to this requirement. Further, in response to this restriction requirement, applicant is requested to further identify (a) any fragments of SEQ ID NO: 66 that are represented in SEQ ID NO: 8 to 54 for examination in claim 3, (b) one of SEQ ID NO: 8 to 54 and 57-65 and 67 to 74 for examination with SEQ ID NO: 66 in claim 5, (c) a primer pair from SEQ ID NO: 1-7 for examination with the method of claim 13.

12. A telephone call was made to BJ Sadoff on 10/7/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

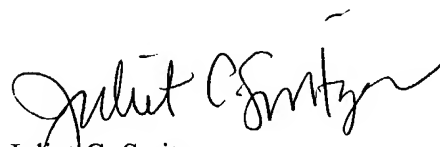
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Examiner
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November 1, 2004